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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,703	04/30/2001	Lucilla Steinaa	3631-0109P	5928

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,703	STEINAA ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/8/03, 4/30/03, 11/13/01, 4/30/01, 4/4/*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *1-66 and 70-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67,68,84,85,87,88,90,91,93 and 94* is/are rejected.

7)☒ Claim(s) *69, 86, 89, 92 and 95* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/30/01* filed 5/29/01
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendments filed 9/8/03, 4/30/03, 11/13/01, 4/30/01, 4/4/01 and Applicant's response filed 6/25/01 are acknowledged and have been entered.

2. Applicant's election with traverse of Group VI (claims 67-69), and species of foreign T_H epitope SEQ ID NO: 12 introduced into SEQ ID NO: 3 in place of the amino acid residues at positions 250-264 in Applicant's amendment filed 4/30/03 is acknowledged.

The basis for the traversal is that the International Preliminary Examination Report does not find lack of unity, and that the reference WO 95/05849 teaches the insertion of T_H epitopes and does not mention class I MHC.

Applicant's arguments have been considered, but are not deemed persuasive for the reasons of record. Further, it is the Examiner's position that WO 95/05849 teaches (on page 6) teach that use of their method leads to the breaking of T cell, i.e., Th and CTL, as well as B cell autotolerance towards the protein. It is the Examiner's further position that the protein contains CTL epitopes.

The requirement is still deemed proper and is therefore made FINAL.

Claims 67-69 and 84-95 read on the elected species.

Upon consideration of the prior art, the search has been extended to include the species recited in claim 69 and SEQ ID NO: 14 recited in claims 93-95.

Claims 67-69 and 84-95 read on the elected species are currently being examined.

Accordingly, claims 1-66, 70-83 (non-elected Groups I-V and VII-VIII) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification, for example, page 119 at lines 26 and 28. It is noted that the specification at the said location discloses amino acid residues of PSM, but the SEQ ID NO for the said PSM is not disclosed at that location; for example, if the amino acid residues are 4-12 or 711-719 of human PSM and human PSM is SEQ ID NO: 2, Applicant is required to so amend the specification.

4. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 60/105,011. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of

the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents.

The first sentence of the specification should refer to the provisional application using language such as:
This application claims the benefit of U.S. Provisional Application No. 60/____, filed ____.
See MPEP 1302.04

If a statutory reference is included in this statement, if must be to 35 USC 119(e) and not to 35 USC 120.

5. The disclosure is objected to because of the following informalities:

The address of ATCC is not disclosed on page 114 at line 16 or on page 115 at line 16. Please note the current address: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Appropriate corrections are required.

6. For the purpose of prior art rejections, the filing date of the instant claim 69 is deemed to be the filing date of the PCT/DK 99/00525 parent application, i.e. 10/5/99, as the parent applications do not support the claimed limitations of the instant application. The limitation wherein the foreign TH epitope is introduced into a part of the Her2 amino acid sequence defined by SEQ ID NO: 3 at the positions recited is not disclosed in the said parent applications.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point

out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 67, 68, 84, 85, 87, 88, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0090379A1 in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

2002/0090379A1 teaches analogues of self proteins that are made immunogenic by inserting foreign T_H cell epitopes, including from tetanus, that are universally recognized, i.e., "promiscuous" recited in instant claims 84 and 85, and that such analogues may be used to treat cancer (especially claim 1, abstract, page 2 at [0015] and column 2 at lines 12-15 of 2002/0090379A1).

2002/0090379A1 does not teach the said analogues wherein the self protein is human Her2.

Fendly et al teach the human Her2/neu protooncogene is amplified and overexpressed in a variety of human adenocarcinomas and a treatment approach is to direct the patients own immune system toward those tumor cells that overexpress Her2. Fendly et al further teach that the extracellular domain (ECD) of Her2 was weakly immunogenic or non-immunogenic when administered in vivo, but could stimulate both humoral and cellular immune responses when administered with Detox adjuvant and could growth inhibit a breast cell tumor line that overexpressed Her2. Fendly et al teach that it is not known if immunogenicity of Her2-ECD is weaker in humans than in rhesus monkeys, but it is conceivable that Her2-ECD given with a potent adjuvant, perhaps combined with other strategies aimed at immunorestoration, can lead to effective immunization (especially page 137, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by Fendly et al with inserted foreign T_H cell epitopes as taught for the self protein analogues of 2002/0090379A1 and to have administered it to humans using the Detox adjuvant of Fendly et al..

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by Fendly et al by directing the patient's own immune system toward those tumor cells that overexpress Her2.

9. Claims 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0090379A1 in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993) as applied to claims 67, 68, 84, 85, 87, 88, 90 and 91 above, and further in view of A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A, and AAR11896 or EP427347A.

US 2002/0090379A1 and Fendly et al have been discussed supra, hereafter "the combined references".

The combined references do not teach wherein the natural T_H epitope has SEQ ID NO: 12 or SEQ ID NO: 14.

A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application.

A_Geneseq_101002 Accession Number AAR11896 or EP427347A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 14 of the instant application.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by the combined references and using the universal T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application taught by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A, or consisting of the sequence of SEQ ID NO: 14 of A_Geneseq_101002 Accession Number AAR11896 or EP427347A.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by the combined references in a variety of persons with diverse HLA haplotypes by using a "universal" T_H epitope taught by by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A.

10. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/05849 (IDS reference) in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

WO 95/05849 teaches analogues of self proteins that are made immunogenic by inserting foreign T_H cell epitopes, including from tetanus, and that such analogues may be used to treat cancer (especially page 3 at lines 20-21, page 5 at lines 10-25, the paragraph spanning pages 6 and 7 and claims 1, 2 and 5).

WO 95/05849 does not teach the said analogues wherein the self protein is human Her2.

Fendly et al teach the human Her2/neu protooncogene is amplified and overexpressed in a variety of human adenocarcinomas and a treatment approach is to direct the patients own immune system toward those tumor cells that overexpress Her2. Fendly et al further teach that the extracellular domain (ECD) of Her2 was weakly immunogenic or non-immunogenic when administered in vivo, but could stimulate both humoral and cellular immune responses when administered with Detox adjuvant and could growth inhibit a breast cell tumor line that overexpressed Her2. Fendly et al teach that it is not known if immunogenicity of Her2-ECD is weaker in humans than in rhesus monkeys, but it is conceivable that Her2-ECD given with a potent adjuvant, perhaps combined with other strategies aimed at immunorestoration, can lead to effective immunization (especially page 137, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by Fendly et al with inserted foreign T_H cell epitopes as taught for the self protein analogues of WO 95/05849 and to have administered it with the adjuvant taught by Fendly et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by Fendly et al by directing the patient's own immune system toward those tumor cells that overexpress Her2 as taught for the self proteins of WO 95/05849.

11. Claims 84, 85, 87, 88, 90, 91, 93, 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/05849 in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993) as applied to claims 67 and 68 above, and further in view of A_Geneseq_101002 Accession Number AAR11896 or EP427347A and AAR06310 or AAW11505 or EP 378881A or WO9640789A.

WO 95/05849 and Fendly et al have been discussed supra, hereafter "the combined references".

The combined references do not teach wherein the natural T_H epitope is promiscuous and has SEQ ID NO: 12 or SEQ ID NO: 14.

A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application.

A_Geneseq_101002 Accession Number AAR11896 or EP427347A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 14 of the instant application.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by the combined references and using the universal T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application taught by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A, or consisting of the sequence of SEQ ID NO: 14 of A_Geneseq_101002 Accession Number AAR11896 or EP427347A.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by the combined references in a variety of persons with diverse HLA haplotypes by using a "universal" T_H epitope taught by by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A.

12. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalum et al (J. Immunol. 157: 4796-4804, 1996) in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Dalum et al teach breaking of B cell tolerance towards a self protein using a foreign T_H cell epitope inserted into the protein, i.e., using an analog of the self protein. Dalum et al further teach that the T cell response was to the inserted epitope as well as to a neoepitope formed by a combination of the inserted epitope and part of the neighboring self protein. Dalum et al teach treatment of diseases by induction of autoantibodies (T cell help for B cell autoantibody production).

Dalum et al do not teach wherein the self protein is human Her2.

Fendly et al teach the human Her2/neu protooncogene is amplified and overexpressed in a variety of human adenocarcinomas and a treatment approach is to direct the patients own immune system toward those tumor cells that overexpress Her2. Fendly et al further teach that the extracellular domain (ECD) of Her2 was weakly immunogenic or non-immunogenic when administered in vivo, but could stimulate both humoral and cellular immune responses when administered with Detox adjuvant and could growth inhibit a breast cell tumor line that overexpressed Her2.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by Fendly et al with inserted foreign T_H cell epitopes as taught for the self protein analogues of Dalum et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by Fendly et al by directing the patient's own immune system toward those tumor cells that overexpress Her2.

13. Claims 84, 85, 87, 88, 90, 91, 93, 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalum et al (J. Immunol. 157: 4796-4804, 1996) in view of Fendly et al (Vaccine Research 2/3, pages 129-139, 1993) as applied to claims 67 and 68 above, and further in view of A_Geneseq_101002 Accession Number AAR11896 or EP427347A and AAR06310 or AAW11505 or EP 378881A or WO9640789A.

Dalum et al and Fendly et al have been discussed supra, hereafter "the combined references".

The combined references do not teach wherein the natural T_H epitope is promiscuous and has SEQ ID NO: 12 or SEQ ID NO: 14.

A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application.

A_Geneseq_101002 Accession Number AAR11896 or EP427347A teach a natural universal, i.e., promiscuous, T_H epitope from tetanus toxoid used to enhance immune response or to induce an immune response to a hapten, the said T_H epitope consisting of the sequence of SEQ ID NO: 14 of the instant application.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made analogues of the Her2 protein taught by the combined references and using the universal T_H epitope consisting of the sequence of SEQ ID NO: 12 of the instant application taught by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A, or consisting of the sequence of SEQ ID NO: 14 of A_Geneseq_101002 Accession Number AAR11896 or EP427347A.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat human adenocarcinomas as taught by the combined references in a variety of persons with diverse HLA haplotypes by using a "universal" T_H epitope taught by by A_Geneseq_101002 Accession Number AAR06310 or AAW11505 or EP 378881A or WO9640789A.

14. Claims 69, 86, 89, 92 and 95 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The references crossed out in the Forms 1449 filed 5/29/01 and 4/30/01 have not been considered because they have not been submitted by Applicant. They will be considered in the next Office Action. It would expedite prosecution if Applicant would send in copies of references.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061 (after 1/7/04 the telephone number is 571-272-0842). The Examiner can normally be reached on Monday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 (before final) or 703-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 27, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600